COMPARISON OF SELECTED INTERMEDIATE CLINICAL MEASURES BY YEARS ON DIALYSIS

Supplemental Report #2

1998 ESRD Core Indicators Project
Opportunities to improve care for adult End-Stage Renal Disease patients

The Health Care Financing Administration *April 1999*

INTRODUCTION

The purpose of the Health Care Financing Administration's (HCFA's) End-Stage Renal Disease (ESRD) Core Indicators Project is to assist providers of ESRD services in assessing and identifying opportunities to improve the care provided to adult (aged $18 years) in-center hemodialysis (HD) and peritoneal dialysis patients.

This supplemental report describes selected intermediate outcomes measures for adult HD patients by categories of years on dialysis.

METHODS

The Sample

In February, 1998, the eighteen Network organizations provided to HCFA a listing of all ESRD patients in their geographic area. All in-center HD patients who were 18 years or older as of September 30, 1997 and alive on December 31, 1997 were identified and eligible for inclusion in the sample. A national random sample, stratified by Network, was selected from this universe of patients.

Data Collection

In June 1998, a one-page data collection form was sent to ESRD facilities providing care to selected patients. Clinical information in the selected patients' medical records was abstracted for each patient in the sample who was receiving in-center HD during the months of October, November, and December, 1997. Patient characteristic information included gender, age, race, Hispanic ethnicity, years on dialysis, and primary cause of ESRD. Clinical information collected to assess the quality of care provided to these patients included the following: patient height, pre- and post-dialysis blood urea nitrogen (BUN) levels and pre- and post-dialysis weights (in kg) to calculate the urea reduction ratio (URR) and Kt/V values, dialysis session length, dialyzer codes (to determine dialyzer KUf), hematocrit values, hemoglobin values, prescribed weekly epoetin alfa doses (units/kg) at the time the hematocrit was drawn, transferrin saturations, ferritin concentrations, iron prescription practices, serum albumin values and the laboratory method used to determine the serum albumin values (bromcresol green [BCG] or bromcresol purple [BCP]).

Completed forms were returned to the appropriate Network office where data were reviewed and entered into a computerized database (Epi Info v. 6.04).[1] The data were forwarded to HCFA for aggregation and analysis.

Data Analysis

Kt/V values were calculated according to the Daugirdis II formula.[2] For this report, percentage, mean (±standard deviation [SD]), and median values were derived from available reported data over the three month study period. Associations of measures with categories of years on dialysis were tested by Chi square, hierarchical ANOVA, and two-tailed student's t-test analyses, with a p-value < 0.05 considered to be significant. For these analyses, racial categories were restricted to Caucasian and African-American groups only, due to the low numbers in the other racial groups.

Logistic regression analysis, stratified by age group (under 65 yrs and 65+ yrs) was conducted on the following intermediate outcome measures: mean URR $65%, mean Kt/V $1.2, mean hematocrit < 28%, mean hematocrit $33%, mean hematocrit 33%-36%, and mean serum albumin $3.5/3.2 gm/dL (BCG/BCP laboratory methods, respectively). The following variables were entered into each logistic regression model in a forward stepwise manner: gender, age (years), race (African-

American and Caucasian only), Hispanic (Yes, No), years on dialysis as a categorical variable (<0.5, 0.5-1, 1-2, and 2+ years, with 2+ years as the referent category), mean pre-dialysis weight in kg, diabetes mellitus listed as a primary cause of ESRD (Yes, No), and Network as a categorical variable. The final models displayed in this report retain only those variables with a statistically significant contribution to the model when controlling for the other demographic and patient characteristic variables listed above (except Network).

Data analyses were conducted utilizing Epi Info, v. 6.04 and SPSS for Windows, v. 8.0.[3]

RESULTS

Patients dialyzing two or more years were significantly younger ($p<0.001$) compared to patients dialyzing less than two years. (Table 1) A significantly larger proportion of patients dialyzing two or more years were African-American and a significantly smaller proportion were Caucasian ($p<0.001$) compared to the group of patients dialyzing less than two years. There was a significantly larger proportion of patients dialyzing two or more years with hypertension as a primary cause of ESRD, and a significantly smaller proportion of patients in this group with diabetes mellitus as a primary cause of ESRD compared to the group of patients dialyzing less than two years ($p<0.001$).

Patients dialyzing less than six months experienced poorer intermediate outcomes compared to patients dialyzing six months or more. (Table 2) Multi variate logistic regression analyses, stratified by age group (less than 65 years and 65 years and older) and controlling for gender, race (Caucasian and African-American only), Hispanic ethnicity, presence of diabetes mellitus as a primary cause of ESRD, pre-dialysis body weight (kg), revealed uniformly that patients dialyzing less than six months were at increased risk for experiencing poorer intermediate outcomes compared to patients dialyzing six months or more. (Tables 3A-F) Similar findings were noted regardless of whether patients were identified as health maintenance organization (HMO) or fee-for-service (FFS) patients.[4]

KEY OBSERVATIONS

- A greater proportion of patients dialyzing two years or more were younger, African-American, and have hypertension as a primary cause of ESRD.
- Patients dialyzing less than six months are at increased risk of experiencing poorer intermediate outcomes among those examined (URR, Kt/V, hematocrit, and serum albumin).
- These findings may be due to poor pre-ESRD care and/or late referral to a nephrologist.

*The lower URR and Kt/V values seen in the group of patients dialyzing six months or less may be a reflection of access issues and/or other factors.

* The lower hematocrit values seen in the group of patients dialyzing six months or less may be due to a greater proportion of these patients not receiving epoetin alfa pre-ESRD.

REFERENCES

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2. Daugirdis JT. Second generation logarithmic estimates of single-pool variable volume Kt/V: an analysis of error. J Am Soc Nephrol 1993;4:1205-1213.

3. Norusis MJ. SPSS for Windows Advanced Statistics. Release 8.0. Chicago, IL. USA. 1997.

4. Comparison of demographic and selected intermediate outcome measures for health maintenance organization (HMO) and fee-for-service (FFS) adult in-center hemodialysis patients. ESRD Core Indicators Project Annual Report. Supplemental Report #1. DHHS. Health Care Financing Administration. Baltimore, MD. February 1999.

TABLE 1: PERCENT OF PATIENTS WITH SELECTED CHARACTERISTICS, AND MEAN VALUES BY DURATION OF DIALYSIS (YEARS)

	DURATION OF DIALYSIS (YEARS)			
PATIENT CHARACTERISTIC	**< 0.5 (n=848)**	**0.5-1 (n=965)**	**1-2 (n=1503)**	**2+ (n=3759)**
TOTAL	**12**	**14**	**21**	**53**
Gender				
Males	54	54	52	53
Females	46	46	48	47
Age (years)				
Mean (±SD)***	61.7 (±14.4)	62.8 (±14.4)	62.0 (±15.2)	59.1 (±15.6)
Median	64	66	64	61
Age group (years)***				
18-44	15	13	15	20
45-64	37	35	35	38
65+	48	52	50	43
Race/Ethnicity***				
Caucasian	62	54	54	47
African-American	27	32	33	42
American Indian/Alaska Native	2	2	2	2
Asian American/Pacific Islander	3	5	5	4
Other/Unknown	7	7	6	5
Hispanic	11	12	11	12
Primary Cause of ESRD***				
Diabetes mellitus	48	48	43	33
Hypertension	22	24	26	30
Glomerulonephritis	9	9	11	16
Other/Unknown	20	18	20	22
Pre-dialysis body weight (in kg)*				
Mean (±SD)	75.3 (±20.7)	74.0 (±18.0)	76.0 (±19.8)	74.4 (±20.0)
Median	72.2	72.1	73.3	71.2

Significant difference among duration of dialysis categories noted by: * $p<0.05$, ** $p<0.01$, *** $p<0.001$

Note: Percents may not add up to 100% due to rounding.

TABLE 2: COMPARISON OF SELECTED CLINICAL MEASURES FOR ADULT IN-CENTER HD PATIENTS BY DURATION OF DIALYSIS (YEARS)

		DURATION OF DIALYSIS (YEARS)			
INTERMEDIATE OUTCOME MEASURE		**<0.5**	**0.5-1**	**1-2**	**2+**
Dialysis Adequacy					
Percent of patients with URR≥65%***		43	68	76	78
mean (±SD) URR (%)***		63.0 (±9.5)	67.3 (±8.5)	68.9 (±7.6)	69.0 (±7.2)
median URR (%)		60.0	70.0	70.0	70.0
Number and percent of patients with Kt/V≥1.2***	49	75	80	85	
mean(±SD) Kt/V***		1.21 (±0.29)	1.36 (±0.27)	1.41 (±0.26)	1.42 (±0.25)
median Kt/V		1.2	1.4	1.4	1.4
mean (±SD) dialysis session length (minutes)**		206.8 (±28.7)	210.1 (±27.6)	210.3 (±31.1)	211.2 (±30.8)
median dialysis session length (minutes)	210	210	210	210	
Percent of patients dialyzed with dialyzer KUf 20+ mL/mm Hg/hr***		44	49	51	52
Anemia Management					
Percent of patients with:					
hematocrit < 28%***		16	6	4	6
hematocrit > 30%***		61	80	82	81
hematocrit ≥ 33%***		41	58	60	59
hematocrit 33%-36%***		34	49	51	48
mean (±SD) hematocrit (%)***		31.7 (±4.0)	33.2 (±3.1)	33.4 (±3.0)	33.5 (±3.5)
median hematocrit (%)		32.0	33.5	33.6	33.6
mean (±SD) hemoglobin (gm/dL)***		10.2 (±1.3)	10.8 (±1.1)	10.9 (±1.1)	10.8 (±1.2)
median hemoglobin (gm/dL)		10.3	10.8	10.9	10.9
Percent of patients with transferrin saturation≥20%***		51	69	73	73
mean (±SD) transferrin saturation (%)***		23.9 (±13.4)	28.1 (±12.3)	30.1 (±13.9)	30.1 (±13.8)
median transferrin saturation (%)		21.0	25.3	27.2	27.7
Percent of patients with serum ferritin concentration≥100 ng/mL***		67	79	84	84
mean (±SD) serum ferritin concentration (ng/mL)***		281.8 (±271.4)	442.2 (±426.1)	550.3 (±492.0)	542.5 (±467.1)
median serum ferritin concentration (ng/mL)					
Percent of patients with transferrin saturation <20% AND serum ferritin concentration < 100 ng/mL***		14	6	4	5
mean (±SD) weekly epoetin alfa dose (units/kg/week)***		209.5 (±126.6)	196.5 (±147.5)	180.6 (±131.4)	193.0 (±145.4)
median weekly Epoetin alfa dose (units/kg/week)		188	159	147	158
Percent of patients prescribed+:					
IV Epoetin alfa***		84	88	86	87
SC Epoetin alfa***		13	12	12	10
IV iron***		58	62	60	55
PO iron***		27	30	27	30
Serum Albumin					
Percent of patients with serum albumin≥3.5/3.2 gm/dL (BCG/BCP laboratory methods^)***		63	81	86	87
mean (±SD) serum albumin (gm/dL) (BCG)***		3.56 (±0.46)	3.77 (±0.40)	3.86 (±0.43)	3.88 (±0.39)
median serum albumin (gm/dL) (BCG)	3.6	3.8	3.9	3.9	
mean (±SD) serum albumin (gm/dL) (BCP)***		3.39 (±0.59)	3.58 (±0.44)	3.63 (±0.48)	3.62 (±0.45)
median serum albumin (gm/dL) (BCP)	3.4	3.6	3.6	3.7	

+ prescribed at least once during the study period (October-December 1997)

^ BCG = bromcresol green laboratory method / BCP = bromcresol purple method

Significant difference among duration of dialysis categories noted by: ** p<0.01, *** p<0.001

TABLE 3A: FINAL LOGISTIC REGRESSION MODEL PREDICTING A MEAN URR$65%

	< 65 years		65+ years		
	Odds Ratio (95%CI)	**p-value**		**Odds Ratio (95% CI)**	**p-value**
Duration of dialysis (years) (2+ years = referent)			Duration of dialysis (years) (2+ years=referent)		
<0.5	0.19 (0.14, 0.24)	<0.001	<0.5	0.16 (0.12, 0.21)	<0.001
0.5-1	0.48 (0.37, 0.61)	<0.001	0.5-1	0.58 (0.44, 0.76)	<0.001
1-2	0.81 (0.66, 1.00)	0.0549	1-2	0.88 (0.68, 1.14)	0.3352
Female Gender	2.3 (1.9, 2.8)	<0.001	Female Gender	1.9 (1.5, 2.3)	<0.001
higher pre-dialysis weight (per kg)	0.973 (0.969, 0.977)	p<0.001	African-American	0.68 (0.55, 0.83)	<0.001
increasing age (per year)	1.01 (1.00, 1.02)	p<0.01	Higher pre-dialysis weight (per kg)	0.980 (0.975, 0.986)	<0.001
African-American	0.84 (0.71, 0.99)	<0.05			

Variables not retained in the model:	p-value	**Variables not retained in the model:**	p-value
Hispanic ethnicity	0.3374	Hispanic ethnicity	0.8140
DM+ (as primary cause of ESRD)	0.1682	Age (per year)	0.2819
		DM+ (as primary cause of ESRD)	0.2151

TABLE 3B: FINAL LOGISTIC REGRESSION MODEL PREDICTING A MEAN KT/V$1.2%

	< 65 years			**65+ years**	
	Odds Ratio (95%CI)	**p-value**		**Odds Ratio (95% CI)**	**p-value**
Duration of dialysis (years) (2+ yrs = referent)			Duration of dialysis (years) (2+ years = referent)		
<0.5	0.14 (0.11, 0.19)	<0.001	<0.5	0.14 (0.11, 0.19)	<0.001
0.5-1	0.39 (0.30, 0.49)	<0.001	0.5-1	0.59 (0.44, 0.80)	<0.001
1-2	0.66 (0.53, 0.82)	<0.001	1-2	0.82 (0.62, 1.1)	0.1642
Female Gender	2.1 (1.8, 2.5)	<0.001	Female Gender	1.5 (1.2, 1.9)	<0.001
higher pre-dialysis weight (per kg)	0.973 (0.969, 0.976)	<0.001	higher pre-dialysis weight (per kg)	0.980 (0.974, 0.986)	<0.001
increasing age (per year)	1.01 (1.00, 1.02)	<0.01	African-American	0.79 (0.63, 0.99)	<0.05

Variables not retained in the model:	p-value	**Variables not retained in the model:**	p-value
DM+ (as primary cause of ESRD)	0.4283	DM+ (as primary cause of ESRD)	0.8696
Hispanic ethnicity	0.1074	Age (per year)	0.7623
Race (Caucasian/African-American only)	0.0641	Hispanic ethnicity	0.5463

TABLE 3C: FINAL LOGISTIC REGRESSION MODEL PREDICTING A MEAN HEMATOCRIT <28%

	< 65 years		**65+ years**		
	Odds Ratio (95%CI)	**p-value**		**Odds Ratio (95% CI)**	**p-value**
Duration of dialysis (years) (2+ years = referent)			Duration of dialysis (years) (2+ years = referent)		
<0.5	3.5 (2.5, 4.8)	<0.001	<0.5	4.4 (2.9, 6.5)	<0.001
0.5-1	1.05 (0.68, 1.6)	0.8236	0.5-1	1.3 (0.79, 2.2)	0.2856
1-2	0.87 (0.60, 1.3)	0.4653	1-2	0.85 (0.52, 1.4)	0.5340
African-American	1.6 (1.2, 2.1)	<0.001	African-American	2.3 (1.6, 3.2)	<0.001
increasing age (per year)	0.98 (0.97, 0.99)	<0.001			

Variables not retained in the model:	p-value	**Variables not retained in the model:**	p-value
DM+ (as primary cause of ESRD)	0.9609	DM+ (as primary cause of ESRD)	0.9138
Pre-dialysis weight per kg	0.4028	Pre-dialysis weight per kg	0.6931
Hispanic ethnicity	0.3993	Hispanic ethnicity	0.2014
Gender	0.0874	Gender	0.1306
		Age (per year)	0.0617

TABLE 3D: FINAL LOGISTIC REGRESSION MODEL PREDICTING A MEAN HEMATOCRIT $33%

	< 65 years			**65+ years**	
	Odds Ratio (95%CI)	**p-value**		**Odds Ratio (95% CI)**	**p-value**
Duration of dialysis (years) (2+ years = referent)			Duration of dialysis (years) (2+ years = referent)		
<0.5	0.42 (0.33, 0.53)	<0.001	<0.5	0.45 (0.36, 0.57)	<0.001
0.5-1	0.95 (0.76, 1.2)	0.6436	0.5-1	0.93 (0.74, 1.15)	0.4923
1-2	0.99 (0.82, 1.2)	0.9067	1-2	0.97 (0.80, 1.2)	0.7593
Female Gender	0.68 (0.59, 0.79)	<0.001	Female gender	0.77 (0.66, 0.89)	<0.001
Hispanic Ethnicity	1.3 (1.0, 1.6)	<0.05	African-American	0.77 (0.65, 0.90)	<0.01
increasing age (per year)	1.008 (1.002, 1.015)	<0.05			
African-American	0.85 (0.73, 0.98)	<0.05			

Variables not retained in the model:	p-value	**Variables not retained in the model:**	p-value
Pre-dialysis weight per kg	0.9538	Pre-dialysis weight per kg	0.5491
DM+ (as primary cause of ESRD)	0.4284	DM+ (as primary cause of ESRD)	0.4840
		Hispanic ethnicity	0.2166
		Age (per year)	0.1625

TABLE 3E: FINAL LOGISTIC REGRESSION MODEL PREDICTING A MEAN HEMATOCRIT 33%-36%

	< 65 years		**65+ years**		
	Odds Ratio (95%CI)	**p-value**		**Odds Ratio (95% CI)**	**p-value**
Duration of dialysis (years) (2+ years = referent)			Duration of dialysis (years) (2+ years = referent)		
<0.5	0.61 (0.49, 0.75)	<0.001	<0.5	0.48 (0.37, 0.60)	<0.001
0.5-1	1.04 (0.85, 1.3)	0.7017	0.5-1	1.03 (0.83, 1.3)	0.8104
1-2	1.1 (0.97, 1.4)	0.1072	1-2	1.03 (0.86, 1.2)	0.7269
			African-American	0.81 (0.69, 0.95)	<0.05

Variables not retained in the model:		**Variables not in the model:**	
	p-value		p-value
DM+ (as primary cause of ESRD)	0.5160	DM+ (as primary cause of ESRD)	0.7992
pre-dialysis weight per kg	0.3818	Hispanic ethnicity	0.6927
Race (Caucasian/African-American only)	0.3754	Pre-dialysis weight per kg	0.3420
Gender	0.2156	Age (per year)	0.0673
Hispanic ethnicity	0.2026	Gender	0.0541
Age (per year)	0.0660		

TABLE 3F: FINAL LOGISTIC REGRESSION MODEL PREDICTING A MEAN SERUM ALBUMIN $ 3.5/3.2GM/DL (BCG/BCP, RESPECTIVELY)

	< 65 years		**65+ years**		
	Odds Ratio (95%CI)	**p-value**		**Odds Ratio (95% CI)**	**p-value**
Duration of dialysis (years) (2+ years = referent)			Duration of dialysis (years) (2+ years = referent)		
<0.5	0.23 (0.18, 0.29)	<0.001	<0.5	0.32 (0.25, 0.42)	<0.001
0.5-1	0.73 (0.54, 0.97)	<0.05	0.5-1	0.68 (0.53, 0.88)	<0.01
1-2	0.82 (0.63, 1.06)	0.1215	1-2	1.2 (0.93, 1.6)	0.1558
DM+ (as primary cause of ESRD)	0.48 (0.39, 0.58)	<0.001	DM+ (as primary cause of ESRD)	0.66 (0.54, 0.80)	<0.001
increasing pre-dialysis body weight (per kg)	1.01 (1.00, 1.02)	<0.001	increasing pre-dialysis body weight (per kg)	1.01 (1.00, 1.02)	<0.001
			Hispanic ethnicity	1.4 (1.01, 1.9)	<0.05
Female gender	0.73 (0.60, 0.88)	<0.01			

Variables not retained in the model:	p-value	**Variables not retained in the model:**	p-value
Race (Caucasian/African-American only)	0.2135	Race (Caucasian/African-American only)	0.8824
Hispanic ethnicity	0.1027	Gender	0.8212
Age (per year)	0.0995	Age (per year)	0.2096